

APPLICATION
FOR
UNITED STATES LETTERS PATENT

PATENT APPLICATION

SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that Frederic P. Field of 5 Woodland Road, North Hampton, NH 03862, Douglas A. Fogg of 15 South Pleasant Street, Merrimac, MA 01860, and Gregory E. Sancoff of 120 Mill Road, North Hampton, NH 03862, have invented certain improvements in SURGICAL SUTURING INSTRUMENT AND METHOD OF USE, of which the following description is a specification.

PS/ONUX17.CVR

SURGICAL SUTURING INSTRUMENT AND METHOD OF USE

Reference To Pending Prior Applications

This is a continuation-in-part of pending prior
5 U.S. Patent Application Serial No. 09/818,300, filed
03/27/01 by Gregory E. Sancoff et al. for SURGICAL
SUTURING INSTRUMENT AND METHOD OF USE (Attorney's
Docket No. ONUX-15), which patent application in turn
claims benefit of (1) prior U.S. Patent Application
10 Serial No. 09/368,273, filed 08/03/99 by Gregory E.
Sancoff et al. for SURGICAL SUTURING INSTRUMENT AND
METHOD OF USE (Attorney's Docket No. ONUX-4), and (2)
prior U.S. Provisional Patent Application Serial No.
60/192,487, filed 3/27/00 by Gregory E. Sancoff et al.
15 for SURGICAL SUTURING INSTRUMENT AND METHOD OF USE
(Attorney's Docket No. ONUX-15 PROV).

This patent application also claims benefit of
pending prior U.S. Provisional Patent application
Serial No. 60/242,166, filed 10/20/00 by Frederic P.
20 Field et al. for SURGICAL SUTURING INSTRUMENT AND
METHOD OF USE (Attorney's Docket No. ONUX-17 PROV).

ONUX-17

This patent application also claims benefit of
pending prior U.S. Provisional Patent Application
Serial No. 60/241,936, filed 10/20/00 by Bruce B. Adams
et al. for SURGICAL SUTURING INSTRUMENT AND METHOD OF
5 USE (Attorney's Docket No. ONUX-18 PROV).

The five above-identified patent applications are
hereby incorporated herein by reference.

Field Of The Invention

10 This invention relates to medical instruments and
procedures in general, and more particularly to
suturing instruments and methods for suturing.

Background Of The Invention

15 Suturing instruments are typically used to secure
together two or more portions of a subject patient
(e.g., tissue such as muscle or skin) or to attach an
object to the patient (e.g., to attach a piece of
surgical mesh to the abdominal wall of the patient
20 during hernia repair surgery).

Certain suturing instruments employ a needle that precedes a length of suture material through a subject.

For example, U.S. Patents Nos. 3,470,875;
5 4,027,608; 4,747,358; 5,308,353; 5,674,230; 5,690,653;
5,759,188; and 5,766,186 generally disclose suturing instruments in which a needle, with trailing suture material, is passed through a subject.

U.S. Patents Nos. 4,890,615; 4,935,027;
10 5,417,700; and 5,728,112 generally disclose suturing instruments in which suture material is passed through the end of a hollow needle after that needle has been passed through a subject.

With all of the foregoing devices, a needle must
15 be passed through the subject in order to deploy the suture. This has the disadvantage that the needle typically leaves a larger hole in the subject than is necessary to accommodate only the suture material itself. In this respect it should be appreciated that
20 it is generally desirable to alter each portion of the

material being sutured (e.g., tissue) as little as possible during the suturing process.

5 A suturing instrument has been devised which permits the suture material itself to pierce the subject without the use of a needle. However, this device does not permit adequate flexibility with regard to the type of fastening which may be effected.

10 More particularly, U.S. Patent No. 5,499,990 discloses a suturing instrument having a pair of jaws at its distal end for clamping together two portions of a subject. A 0.25 mm stainless steel suturing wire is advanced to the distal end of the suturing instrument, whereupon the distal end of the suturing wire is caused to travel in a spiral direction so as to create stitches joining together the two portions of the subject. After the spiral is formed, the beginning and end portions of the suture may be bent toward the tissue in order to inhibit retraction of the suture wire into the tissue upon removal of the suturing instrument. The stainless steel wire is sufficiently firm to hold this locking set. In

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addition, after the spiral is formed, the radius of the deployed suture spiral may then be decreased by advancing an outer tube over a portion of the distal end of the instrument. Again, the stainless steel wire is sufficiently firm to hold this reducing set.

Unfortunately, however, such a system does not permit adequate flexibility with regard to the type of fastening which may be effected. More particularly, the suturing instrument of U.S. Patent No. 5,499,990 must clamp the two portions of the subject between its two jaws in order to effect suturing. Such a construction can be inadequate where it is difficult or even impossible to clamp the two portions of the subject between the instrument's jaws, e.g., where the two portions of the subject are too thick to be spanned by the jaws, or where the angle of approach prevents the jaws from clamping together the two portions of the subject, etc.

U.S. Patent No. 4,453,661 discloses a surgical instrument having a pair of jaws at its distal end for clamping together two portions of a subject and

applying staples thereto. The staples are formed from the distal end of a length of wire. More particularly, the distal end of the wire is passed through a subject and thereafter contacts a die that causes the wire to bend, thereby forming the staple. The wire is sufficiently firm to take on the set imposed by the die. The staple portion is then cut away from the remainder of the wire by a knife.

Again, such a system suffers from the fact that it does not permit adequate flexibility with regard to the type of fastening which may be effected, since the surgical instrument must clamp the two portions of the subject between its two jaws in order to effect stapling, and this can be difficult or even impossible to achieve in certain circumstances, e.g., where the two portions of the subject are too thick to be spanned by the jaws, or where the angle of approach prevents clamping, etc.

There is a need, therefore, for a new suturing device that permits minimally disruptive suturing and

provides increased flexibility in the application of the suture material.

Summary Of The Invention

5 The present invention comprises a novel device and method for deploying a flexible elongated element through a subject so as to effect suturing.

10 In one embodiment of the invention, the device includes a proximal end and a distal end, and an advancement unit for longitudinally advancing the flexible elongated element toward the distal end of the device such that a distal end of the flexible elongated element may exit from the distal end of the device with sufficient force to pass through the subject. The device also includes a curved die at the distal end of the device for imparting a looping configuration to portions of the flexible elongated element exiting the distal end of the device, and a curved guide at the distal end of the device for receiving the looped flexible elongated element as it returns to the distal end of the device. In a further

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feature of the invention, a cutting mechanism is provided to permit the looped flexible elongated element to be separated from the remainder of the flexible elongated element. And in a further feature of the invention, the cutting mechanism is adapted to deform both the leading end and the trailing end of the looped flexible elongated element so that each end is forced distally, toward the subject being sutured.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts, and further wherein:

Fig. 1 is a side view showing a suturing instrument formed in accordance with the present invention;

Figs. 2-5 are various views showing various details of the suturing instrument's handle assembly;

Figs. 6-16 are various views showing various details of the suturing instrument's cannula assembly;

5 Fig. 17 - this figure number has not been used in the application;

Figs. 18-21 are various views showing various details of the suturing instrument's wire drive assembly;

10 Figs. 22-25 are various views showing various details of the suturing instrument's wire supply cartridge;

Figs. 26-33 show various steps in a suturing operation conducted with the suturing instrument;

15 Fig. 34 - this figure number has not been used in the application; and

Figs. 35-37 are schematic side views illustrating the interrelationship between the geometry of the cannula assembly's end effector portion and the leading tip of the suture wire.

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Detailed Description Of The Preferred Embodiment

Overview

Looking first at Figs. 1-5, there is shown a
5 suturing instrument 2 which comprises one preferred
embodiment of the present invention. Suturing
instrument 2 generally comprises a handle assembly
100, a cannula assembly 200, a wire drive assembly 300
(Fig. 5) and a wire supply cartridge 400, as will
10 hereinafter be described in further detail.

Among other things, handle assembly 100 comprises
a handle 102 and a lever 104, and cannula assembly 200
comprises a shaft 202, an end effector 204 and a wire
cutting mechanism 206, as will also hereinafter be
15 described in further detail.

As will be discussed in further detail below,
generally during use, the suturing instrument's end
effector 204 is positioned adjacent to the subject
which is to be sutured. Then lever 104 is squeezed
20 towards handle 102, causing wire drive assembly 300 to
draw suture wire out of wire supply cartridge 400 and

push the suture wire distally through cannula assembly
200 to end effector 204, where the suture wire exits
the instrument with sufficient force to pass through
the subject. End effector 204 includes a curved die
5 for imparting a looping configuration to the portions
of the suture wire exiting the distal end of the
instrument, and a curved guide for receiving the
looped suture wire as it returns to the distal end of
the instrument. The looped suture wire may then be
10 cut off, at end effector 204, from the remaining
suture wire that extends back through the suturing
instrument. Such cutting is preferably automatically
effected by wire cutting mechanism 206 at the
conclusion of the lever's stroke.

15 As will be discussed in further detail below,
wire supply cartridge 400 may be supplied separately
from suturing instrument 2, with wire supply cartridge
400 being loaded into suturing instrument 2 prior to
commencing a suturing operation. As will also be
20 discussed in further detail below, wire supply

cartridge 400 may be disposable, such that the cartridge may be discarded after use.

Handle Assembly 100

5 Still looking at Figs. 1-5, handle assembly 100 comprises a housing 106, with the aforementioned handle 102 being fixedly attached to housing 106 and the aforementioned lever 104 being pivotally connected to housing 106 by a pivot pin 108.

10 The inner end of lever 104 includes a slot 110 for receiving a roll pin 112 therein. Roll pin 112 is also secured to a rack 114. Rack 114 is connected to a compression spring 116 at its distal end. Rack 114 includes a length of teeth 118 intermediate to its
15 length, followed by a smooth wall 120 adjacent to its proximal end. As a result of this construction, compression spring 116 normally biases rack 114 proximally, so that lever 104 is biased away from handle 102; however, lever 104 may be squeezed toward
20 handle 102 so as to overcome the force of spring 116, whereby to move rack 114 distally. A pawl 122 (Fig.

3), riding on lever 104 and engaging a set of teeth 124, ensures that lever 104 cannot return to its proximal starting position without moving through one complete stroke. A removable shroud 126 selectively closes off the proximal end of housing 106. The removable nature of shroud 126 permits a fresh wire supply cartridge 400 to be loaded into the suturing instrument and an exhausted wire supply cartridge to be removed from the instrument, as will hereinafter be discussed in further detail.

Cannula Assembly 200

Cannula assembly 200 is shown in greater detail in Figs. 6-16. As noted above, cannula assembly 200 (Fig. 2) comprises shaft 202, end effector 204 and wire cutting mechanism 206.

More particularly, shaft 202 comprises a tube 208 having a distal end 210 and a proximal end 212. A mount 214 is secured to tube 208 near its proximal end whereby shaft 202, and hence the entire cannula assembly 200, may be removably attached to housing 106

of handle assembly 100. Mount 214 includes a flushing port 216 (Fig. 7), communicating with the interior of tube 208 via an opening 218 (Fig. 8), for cleaning the interior of cannula assembly 200. A cap 220

5 selectively closes off flushing port 216.

End effector 204 is secured to the distal end of tube 208.

End effector 204 is configured so as to form a modified suture loop 204, sometimes referred to as a suture clip or a "B-form loop" or a "B-form clip", as
10 will hereinafter be discussed.

More particularly, in this version of the invention, end effector 204 comprises a fixed first portion 222 and a fixed second portion 224.

15 As seen in Fig. 10, fixed first portion 222 includes a first channel 226 for receiving the distal end of the aforementioned wire supply cartridge 400, a smaller diameter second channel 228 for supporting suture wire as the suture wire emerges from wire
20 supply cartridge 400, a third channel 230 for receiving suture wire after the suture wire passes by

cutting bar channel 232 and for imparting a selected curvature to the suture wire, whereby to form suture loop, as will hereinafter be discussed in further detail, and a fourth channel 233 for receiving the
5 returning end of suture wire, as will hereinafter be discussed. Channels 228, 230 and 233 are coplanar. In addition to the foregoing, material is removed from first portion 222 at the locations 234, 235 and 236 so as to effectively form a pair of islands 237A and 237B
10 at the distal end of end effector 204.

In order to assist the controlled retention of suture wire during its travel within channels 228, 230 and 233, these channels may be given an undercut profile such as dovetail (Figs. 11A and 11B), dovetail
15 with flat (Figs. 11C and 11D), T-slot (Figs. 11E and 11F), and/or T-slot with flat (Figs. 11E and 11F). At the same time, in order to minimize harmful friction between suture wire 58 and fixed first portion 222, channel 235 may be widened slightly at locations other
20 than 240 (Fig. 10); locations 240 are, for this particular clip form, contact points for wire bending

(other particular clip forms may have other contact points). In addition, in order to facilitate easy release of a formed suture clip from the tool, the proximal ends of islands 237A and 237B may be relieved slightly at 242 (Fig. 10).

Wire cutting mechanism 206 comprises a cutting bar 246 (Figs. 2 and 14-16). The distal end of cutting bar 246 is disposed in the aforementioned cutting bar channel 232 and the proximal end of cutting bar 246 protrudes from the proximal end 212 of tube 208 (Figs. 2 and 8).

The distal end of cutting bar 246 (Figs. 14-16) preferably comprises a plurality of distinct faces, i.e., a cutting face 248 defining a cutting edge 250, a relief face 252 set at an angle α to cutting face 248, an ejection ramp face 254, and an ejection push face 258. As will hereinafter be discussed in further detail, when cutting bar 246 is driven distally so as to encounter suture wire extending between second channel 228 and third channel 230 (and hence across cutting bar channel 232), cutting edge 250 will sever.

the suture wire, ejection ramp face 254 will lift the trailing end of the severed suture wire out of cutting bar channel 232 and up over island 236 so that the loop may be released from the distal end of the suturing instrument, and ejection push face 258 will push the suture loop free from the distal end of suturing instrument 2.

The proximal end of cutting bar 246 comprises a pusher element 260 (Figs. 2 and 8) adapted to be engaged by lever 104 when cannula assembly 200 is mounted to handle assembly 100 and lever 104 is pulled toward handle 102, whereby to move cutting bar 246 distally within cannula assembly 200. A compression spring 262 is located between pusher element 260 and mount 214 so as to bias cutting bar 246 proximally. As will hereinafter be discussed in further detail, the operations of lever 104 and wire cutting mechanism 206 are preferably coordinated with one another so that pusher element 260 is not engaged by lever 104 until the later part of the lever's stroke, so that

advancement of the suture wire will have ceased by the time cutting bar 246 is activated.

Looking now at Fig. 12, fixed second portion 224 includes a slot 264 which extends proximally from the distal end of the tool. Slot 264 is sized so that when first fixed portion 222 is engaging second fixed portion 224, a gap slightly wider than the diameter of suture wire will be formed between the tops of islands and the opposing material of fixed second portion 224, in order to permit a formed loop to be released from the end of the suturing tool, as will also hereinafter be discussed.

Fixed first portion 222 and fixed second portion 224 are preferably formed out of material which is harder than the suture wire passing through channels 228, 230 and 233, so as to minimize wear on the tool.

Figs. 11I and 11K illustrate further details regarding alternative end effector 204.

Wire Drive Assembly 300

Looking next at Figs. 4, 5 and 18-21, wire drive assembly 300 comprises a fixed block 302, a movable block 304, a first drive shaft roller 306 connected to a spur gear 308 via an axle 310 passing through fixed block 302 and a one way clutch 312, and a second drive shaft roller 314 connected to a spur gear 316 via an axle 318 and a one way clutch 320. A pair of capture blocks 322 and 324 rotatably capture drive shaft rollers 306 and 314 to blocks 302 and 304, respectively.

Movable block 304 is slidably mounted to fixed block 302 via a pair of rods 326 and 328 that pass through movable block 304, fixed block 302 and are secured to a cam follower 330, with springs 332 and 334 biasing movable block 304 into engagement with fixed block 302. A lever 336 and cam 338 are provided for manually forcing movable block 304 away from fixed block 302, and hence drive shaft roller 314 away from drive shaft roller 306, and hence spur gear 316 away from spur gear 308.

Wire drive assembly 300 is normally disposed in handle assembly 100 so that spur gear 308 and 316 engage the teeth 118 of rack 114, and so that drive shaft roller 314 is in substantial engagement with drive shaft roller 306.

However, depressing lever 336 will cause cam follower 338 to pivot, whereby to force movable block 304 away from fixed block 302 and whereby to separate roller 314 from roller 306 (and to separate spur gear 316 from spur gear 308). Wire supply cartridge 400 may then be inserted between rollers 314 and 306 and, by then restoring lever 336 to its inboard position, cause the suture wire to be gripped by rollers 306 and 314, whereupon the suture wire may be driven by rollers 306 and 314 out the distal end of the suturing instrument.

More particularly, after a fresh wire supply cartridge 400 has been installed in the instrument, suture wire may be driven out the distal end of the instrument by depressing lever 104 toward handle 102. Depressing lever 104 toward handle 102 causes roll pin

112 (Fig. 2) to ride within slot 110. More particularly, as the top end of lever 104 moves about pivot pin 108, roll pin 112 moves through slot 110. This causes rack 114 to move distally, which in turn
5 causes spur gears 308 and 316 to rotate, which in turn causes rollers 306 and 314 to rotate, which in turn causes a length of suture wire to be advanced out the distal end of the suturing instrument.

As lever 104 continues to rotate, the toothless
10 region of rack 114 (i.e., the smooth wall 120 at the proximal end of rack 114) is advanced to spur gears 308 and 316, whereby rotation of rollers 306 and 314 will cease and suture wire will no longer be advanced out the distal end of the suturing instrument. Thus
15 it will be seen that by carefully regulating the length of the rack's teeth 118, the length of suture wire ejected from the instrument can also be regulated.

Further movement of lever 104 will then cause the
20 cutting bar's pusher element 260 (Fig. 2) to be engaged, whereby cutting bar 246 will sever the formed

loop of suture wire from the suture wire remaining in the instrument, lift the trailing end of the suture loop and then push the suture loop free from the suturing instrument.

5 At the completion of the stroke, lever 104 is released, thereby allowing the aforementioned parts to return to their starting position under the influence of spring 116. However, one way clutches 312 and 320 (Fig. 19) interposed between drive rollers 306 and 10 314, and the drive rollers 306 and 314, respectively, prevent reverse movement of the drive rollers, thereby preventing any retraction of the suture wire.

 Thus, a single throw of lever 104 will result in a pre-determined degree of movement of drive rollers 15 306 and 314, which will in turn result in a pre-determined length of suture wire being advanced out of the distal end of the suturing instrument.

 It should be appreciated that each drive roller and axle assembly (i.e., drive roller 306 and axle 20 310, and drive roller 314 and axle 318) is preferably machined (i.e., turned) from a single, continuous

piece of metal, using the same tool setup, so that the alignment of both is immune from the inaccuracies which might occur if they were turned at different occasions and assembled using holes and holding means.

5 This construction is important, because the drive rollers are approximately 30 times the diameter of the suture wire they are driving and even the slightest alignment inaccuracies can rotate the wire as it is moved forward. Since the wire is permanently curved
10 by the exit path in the end effector 204, any such wire rotation may cause the wire to swerve from its normal trajectory from the end effector and possibly prevent the leading tip of the wire from properly returning to the end effector after it has passed
15 through the subject.

It should also be appreciated that peripheral grooves may be formed in drive rollers 306 and 314. Such grooves provide a seat for the suture wire being driven and help increase the surface area contact
20 between the drive rollers and the suture wire.

Wire Supply Cartridge 400

Looking next at Figs. 22-25, wire supply cartridge 400 generally comprises a spool housing 402, a wire spool 404, a spool retainer spring 406, a spool cover 408, a molded tube support 410 and a wire support tube 412. A length of suture wire 416 extends from spool 404 and through molded tube support 410 and wire support tube 412.

More particularly, a supply coil of suture wire 416 (comprising wire formed of metal or any other suitable material having the required flexibility and stiffness) may be supplied in the base of cartridge 400 and is fed into wire support tube 412. Wire support tube 412 surrounds suture wire 416 from spool housing 402 to the distal end of suturing instrument 2 where, with the distal end of wire support tube 412 received in channel 226, the suture wire enters second channel 228 in end effector 204. Wire support tube 412 ensures that suture wire 416 does not bend or buckle as the suture wire is pushed through handle assembly 100 and cannula assembly 200. More

particularly, wire support tube 412 preferably forms a sufficiently close sliding fit with suture wire 416 such that suture wire 416 cannot bend or buckle as the suture wire is advanced through suturing instrument 2.

5 At the same time, wire support tube 412 is also formed so as to present a minimum of friction to suture wire 416 as the suture wire is advanced through the instrument. The foregoing characteristics are important, inasmuch as suture wire 416 is extremely
10 thin and flexible and highly susceptible to bending or buckling in the absence of some sort of lateral support.

By way of example but not limitation, where suture wire 416 is formed out of stainless steel and
15 has a diameter of 0.017 inch, wire support tube 412 might have an inside diameter of 0.185 inch and an outside diameter of 0.050 inch. In addition, wire support tube 412 is preferably formed out of 316 stainless steel, however, it may alternatively be
20 formed out of some other material. If desired, the interior of wire support tube 412 may be coated with a

lubricant so as to facilitate closely-supported, low-friction passage of the suture wire through the wire support tube.

Wire support tube 412 and its surrounding molded tube support 410 have aligned openings 418 and 420, respectively, on opposite sides thereof. Openings 418 and 420 expose diametrically opposed portions of the suture wire 416 so that rollers 306 and 314 may contact suture wire 416 and urge the suture wire forward toward the distal end of suturing instrument 2, as will hereinafter be discussed in further detail.

As noted above, wire supply cartridge 400 may be loaded into wire drive assembly 300 by actuating lever 336 so as to force movable block 304 away from fixed block 302 and thereby separate rollers 306 and 314.

Once roller 314 is separated from roller 306 by a sufficient distance, wire support tube 412 may be inserted between rollers 306 and 314, and then roller 314 returned towards roller 306 such that rollers 306 and 314 contact either side of suture wire 416 through the aligned openings 418 and 420 formed in either side

of wire support tube 412 and its surrounding molded support tube 410, respectively.

Operation

5 Suturing instrument 2 may be used to apply loops 422 of wire suture 416 to a subject so as to effect a desired suturing operation.

10 By way of example but not limitation, and looking now at Figs. 26-33, suturing instrument 2 may be used to suture together two portions 500, 502 of a subject which is to be sutured. In a typical case, portions 500, 502 might comprise two sections of severed tissue which need to be re-attached to one another, or two pieces of previously unattached tissue which need to be attached to one another. However, one or the other of the portions 500, 502 might also comprise artificial mesh or some other object which is to be attached to tissue, etc. In addition, in a typical case, portions 500, 502 might be located relatively deep within a patient, and might be accessed during an endoscopic or a so-called "minimally invasive" or a

so-called "closed surgery", procedure; however, in other circumstances, portions 500, 502 might be accessed during a conventional, or so-called "open surgery", procedure. This latter situation might include procedures done at the outer surface of the patient's body, i.e., where portions 500, 502 comprise surface elements.

In any case, suturing instrument 2 is initially prepared for use by installing a wire supply cartridge 400 into the suturing instrument, if a cartridge 400 is not yet installed. As noted above, wire supply cartridge 400 is installed in suturing instrument 2 by (1) removing shroud 126, (2) moving the wire drive assembly's release lever 336 to its open position, so as to move rollers 306 and 314 apart; (3) passing the distal end of the cartridge (i.e., the distal end of wire support tube 412) through wire drive assembly 300 and cannula assembly 200 until the distal end of wire support tube 412 is located in the end effector's first channel 226, at which point the cartridge's molded tube support 410 will be positioned

intermediate rollers 306 and 314; and (4) moving the wire drive assembly's release lever 336 back to its closed position, so that rollers 306 and 314 engage the suture wire 416 through openings 420 and 418, and so that spur gears 308 and 316 engage the teeth 118 of rack 114.

At this point suturing instrument 2 will be ready for use.

When suturing instrument 2 is to apply a suture loop 422 to a subject, the distal end of the suturing instrument is positioned against the subject, e.g., it is positioned against portions 500, 502 (Fig. 10).

End effector 204 is placed against the two pieces of tissue so that channels 230, 233 contact, or substantially contact, the material to be joined, with channel 230 facing one piece of material (e.g., tissue 500) and channel 233 facing the second piece of material (e.g., tissue 502). If desired, end effector 204 may be provided with one or more pins 280 (Fig. 11J) extending distally from its distal end; pins 280 can help stabilize the suturing tool against the

tissue. In addition, pins 280 can hold a prosthesis (e.g., herein mesh) taut against the tissue as the suture wire penetrates it.

5 Next, as shown in Figs. 26 and 27, suture wire is advanced out of wire guide 412, along channel 228, across cutting bar passageway 232, along channel 230, and then out of the tool. Due to the curved geometry of channel 230, the suture wire emerging from end effector 204 will take on a set, causing it to curl in
10 a loop fashion, whereby the suture wire will pass through the material to be sutured and then back into channel 233, in the manner shown in Figs. 28 and 29.

15 If desired, channel 233 can act as a sort of deflecting anvil to receive and redirect the wire received from channel 235. In such cases, channel 233 actually helps form loop 422. However, in accordance with the present invention, it is not necessary for channel 233 to act as a deflecting anvil for wire, since the curvature of loop 233 can be imparted solely
20 by the geometry of channel 230 if desired.

Suture wire is advanced a predetermined amount,
i.e., exactly the right amount to form the desired
loop construct. In other words, where a "B-form loop"
432 is being formed, suture wire is advanced until the
5 leading end of the suture wire passes across cutting
bar passageway 232 and encounters the trailing portion
of the suture wire at the point where the suture wire
crosses cutting bar passageway 232, which causes the
leading tip 285 (Fig. 28 and 29) of the suture wire to
10 be deflected distally into the relieved region 234.
At this point the advancement of suture wire is
stopped.

Next, cutting bar 246 is moved distally. This
causes the cutting bar to (i) first encounter, and
15 sever, the proximalmost portion 290 of the suture wire
extending across cutting bar passageway 232 (Fig. 10),
whereby to separate loop 422 from the remainder of the
suture wire carried by the suturing tool, and (ii)
then drive against the two ends 285, 290 of loop 422
20 whereby, with the assistance of islands 237A and 237B,

respectively, to bend the ends 285 and 290 toward the material being jointed (Figs. 31 and 32).

Significantly, at the same time that this is occurring, inasmuch as cutting bar 246 includes an
5 ejection ramp at the distal end thereof, and inasmuch as the end effector's fixed second portion 224 includes a slot 264 (Fig. 12) to form a gap in the end of the end effector, distal movement of cutting bar 246 will also serve to lift loop 422 over islands
10 237A, 237B, whereby to disengage the formed loop 422 from the end of suturing tool 422. Furthermore, if desired, cutting bar passageway 232 may be offset from the plane of wire channels 228, 230 and 233 so as to further assist lifting loop 422 over islands 237A,
15 237B. In addition, if desired, islands 237A and 237B may be formed so as to be mechanically retractable into the body of fixed first portion 222, whereby to facilitate disengagement of the formed loop 422 from the tool.

20 Due to the manner in which loop 422 is formed, the ends 285 and 290 of the loop will project

distally, into the material being formed, in the manner shown in Fig. 13. This feature is generally highly desirable, since it produces a secure, low profile fixation.

5 If desired, loop 422 can be used to secure mesh 295 (Fig. 33) to tissue, or to attach other objects to tissue, or to attach objects other than tissue together, etc. In this respect it should be appreciated that where the suturing instrument is to
10 be used to secure mesh to tissue, and where end effector 204 is provided with one or more distal stabilizing pins 280 (Fig. 12), pins 280 are preferably formed long enough to extend completely through the mesh and contact the underlying tissue.

15 Various factors can affect how the wire element loops in the tissue. These factors include instrument-related factors (e.g., the curvature of third channel 230, etc.), wire-related factors (e.g., wire tensile strength, wire yield stress, wire
20 diameter, etc.) and tissue-related factors (e.g.,

tissue density, tissue elasticity, tissue thickness, tissue stabilization, etc.).

The aforementioned factors are preferably taken into account when forming wire loops in tissue. For example, when forming a loop in intestine, which tends to be a relatively delicate tissue, it is generally preferable to use a relatively "soft" wire; correspondingly, when forming a loop in the abdominal wall, which tends to be a relatively tough tissue, it is generally preferable to use a relatively "hard" wire.

In general, it has been found that suture wire formed out of 316 LVM stainless steel, having a tensile strength of 230-260 kpsi and a diameter of about 0.006-0.019 inch, is advantageous in particular applications. In general, when forming suture loops with a diameter of about 0.140-0.165 inch, it has been found acceptable to provide third channel 230 with a radius of 0.050-0.075 inch.

It should be appreciated that the suture loop 422 can, if desired, have a diameter which exceeds the diameter of suturing instrument.

5 It should also be appreciated that, due to the fact that cannula assembly 200 can be dismounted from handle assembly 100, a set of different cannula assemblies, each having different loop-forming characteristics, can be provided to the user for appropriate selection at the time of use.

10 In a similar fashion, due to the fact that wire supply cartridge 400 can be dismounted from suturing instrument 2, a set of different wire supply cartridges, each having different suture wire characteristics (e.g., material, hardness, diameter, etc.) can be provided to the user for appropriate
15 selection at the time of use.

If desired, loop 422 can be used to secure mesh 502 to tissue 500, or to attach other objects to tissue, or to attach objects other than tissue
20 together, etc. In this respect it should be appreciated that where the suturing instrument is to

be used to secure mesh to tissue, and where end effector 204 is provided with stabilizing projections 272, 274 (Fig. 12), projections 272, 274 are preferably formed narrow enough and long enough to extend completely through the mesh and contact the underlying tissue.

As noted above, channels 228 and 230 are positioned on opposing sides of cutting bar channel 232, whereby a length of suture wire 416, extending between channels 228 and 230, may be severed by cutting bar 246. In this respect it will be appreciated that the angle at which cutting bar channel 232 intersects channel 228 has a bearing on the angle imparted to the leading tip 424 of suture wire 416. More particularly, in Fig. 35 it will be seen that cutting bar channel 232 intersects second channel 228 at the angle θ ; as a result, the leading tip of suture wire 416 will also be set at the angle θ .

In general, when considered solely from the standpoint of tissue penetration, it is typically

desirable that the angle θ be as small as possible, in order that the suture wire have the sharpest possible tip to facilitate tissue penetration. At the same time, however, it must also be appreciated that the leading tip of suture wire 416 must traverse the substantial curvature of third channel 230 and, if the angle θ is too small, the sharp leading tip of the suture wire will strike the wall of third channel 230 (Fig. 36) and thereby become damaged and/or blunted.

On the other hand, if the angle θ is increased, the heel of the tip will engage the wall of third channel 230 (Fig. 37), thereby leaving the sharp tip of the suture wire undamaged. Thus, it is generally preferred that the angle θ be set so that the leading tip of suture wire 416 be formed as sharp as possible while still being able to traverse the curvature of third channel 230 without damage.

As noted above, suture loop 422 can be used to secure tissue to tissue, or to secure an inanimate object to tissue, or to secure an inanimate object to an inanimate object, etc. In this respect it should

be appreciated that one anticipated application for suture loop 422 is to secure a prosthetic cardiac valve to a valve seat within the heart.

5 In the foregoing description, suture wire 416 is described as comprising an elongated length which is cut into specific lengths at the time of use by the action of cutting bar 246. In this respect it should also be appreciated, however, that suture wire 416 may be pre-cut into selected lengths prior to use, and the
10 pre-cut lengths then stored in a magazine or the like, for deployment at the time of use. In such a case, cutting bar 246 will act as a forming and ejecting tool rather than as a cutting, forming and ejecting tool.

15 As noted above, suture wire 416 may comprise a wire formed out of a metal or any other suitable material having the required flexibility and stiffness. By way of example but not limitation, suture wire 416 may comprise stainless steel,
20 titanium, tantalum, etc.

If desired, suture wire 416 may also be coated with various active agents. For example, suture wire 416 may be coated with an anti-inflammatory agent, or an anti-coagulant agent, or an antibiotic, or a radioactive agent, etc.

Modifications

It will be appreciated by those skilled in the art that numerous modifications and variations may be made to the above-disclosed embodiments without departing from the spirit and scope of the present invention.

Thus, for example, shaft 202 has been shown as being substantially straight; however, it is also anticipated that shaft 202 may be curved along its length. Furthermore, shaft 202 may be substantially rigid, or it may be flexible so that it can be bent along its length. It is also possible to form shaft 202 so that it has two or more articulating sections so as to aid in the positioning of end effector 204.